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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,796	01/11/2002	Naida M. Loskutoff	13511.1USU1	8344

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EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1657

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/044,796

Applicant(s)

LOSKUTOFF ET AL.

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 9, 11, 14, 21, 22, 24-26 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 9, 11, 14, 21, 22, 24-26, 28-31 and 3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/18/2006 has been entered.

Claims 1, 2, 4, 5, 9, 11, 14, 21, 22, 24-26, 28-31 and 33 as amended (0/18/2006) are pending and under examination.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 2, 4, 11, 14, 21, 22, 24-26 and 28-30 as amended remain/are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 685 556 (Ghazarian).

Claims are directed to a semen extender composition that is substantially free from animal products and that comprises 0.1-6% of phospholipid derived from non-animal source comprising lecithin; 0.0001-1% of anionic surfactant; 0.5-3% of carbohydrate; 3-14% of freeze-agent or glycerol; a buffer to provide for pH of about 6.9-7.2 and osmolarity of about 250-350 mOsm. Some claims are further drawn to the use of 90% water in the composition. Some claims are further drawn to incorporation of a generic antioxidant. Some claims are further drawn to incorporation of semen into the semen extender composition. Some claims are/are further drawn to the method of making the semen extender composition by mixing the components of the composition.

EP 0 685 556 (Ghazarian) discloses a semen extender composition that is substantially free from animal products and that contains soybean lecithin. The soybean lecithin is anionic surfactant and it is also antioxidant. The semen extender composition also contains a mixture of Tris and sodium citrate that is both surfactant and buffer. The semen extender composition contains carbohydrate component, for example: s glucose, fructose or lactose and the freeze agent component, for example: as glycerol (see EP page 3, lines 4-16; or see translation page 6). The amounts of ingredients in the cited semen extender composition are within the ranges of the claimed semen extender composition, for example: about 0.6-0.8% of phospholipids such as lecithin, about 0.6-0.8% of anionic surfactant such as lecithin; extra 0.3-0.4% of surfactant such as Tris; about 0.5% of total carbohydrate, about 6-7% of freeze-agent or glycerol, about 0.6-0.8% of antioxidant such as lecithin. Although the cited patent is silent with regard to pH and osmolarity of the semen extender composition and/or solution for semen preservation, the values of pH and osmolarity that are claimed are regular parameters that are commonly used for animal cell culture maintenance and preservation. The cited EP patent also teaches the method of making the semen extender composition by mixing the components of the composition. The cited EP patent also teaches incorporation of semen into the semen extender composition (example 3).

Thus, the cited patent EP 0 685 556 anticipates the presently claimed invention.

2. Claims 1, 2, 4, 5, 11, 14, 21, 22, 24-26 and 28-30 as amended remain/are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,368,786 (Saint-Ramon et al.).

Claims 1, 2, 4, 11, 14, 21, 22, 24-26 and 28-30 as explained above. Claim 5 is further drawn to incorporation of antioxidant such as vitamin A into the semen extender composition.

US 6,368,786 teaches a semen extender composition that is substantially free from animal products and comprises a non-animal derived phospholipid such as lecithin, surfactant, carbohydrate and buffer to provide for pH of about 6.9-7.2 and osmolarity of about 250-350 mOsm, for example: the diluent compositions as disclosed in the tables at col. 3 and 4. The amounts and /or concentrations of ingredients in the cited semen extender composition are within the ranges of the claimed semen extender composition. At least one diluent composition is identical to the composition of the cited above EP 0 685 556 (see example 4 of US'786). Thus, amount of major components are identical as explained above. The diluent composition of the US'786 comprises antioxidant such as vitamin A accompanied by emulsifier Tween 80 (col. 1, lines 49-56). The cited US'786 also teaches the method of making the semen extender composition by mixing the components of the composition. The cited US patent also teaches incorporation of semen into the semen extender composition (example 3).

Thus, the cited patent US 6,368,786 (Saint-Ramon et al.) anticipates the presently claimed invention.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4, 5, 9, 11, 14, 21, 22, 24-26, 28-31 and 33 as amended remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 685 556 [Ghazarian] or US 6,368,786

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[Saint-Ramon et al] taken with US 3,444,039 [Rajamannan], US 6,130,034 [Aitken], US 6,140,121 [Ellington et al] and the reference by Hellmann et al. [Zuchthg., (1988), 23:33-37; IDS reference] for the reasons as explained in the prior office action and for the reasons below.

Claims are directed to a semen extender composition that is substantially free from animal products and comprises a non-animal derived phospholipid such as lecithin in amounts of about 0.1-6%; 0.0001-1% of surfactant; about 0.5-3% of carbohydrate, about 3-14% of freeze-agent such as glycerol; a buffer to provide for pH of about 6.9-7.2 and osmolarity of about 250-350 mOsm. Some claims are further drawn to the use of 90% water in the composition. Some claims are further drawn to incorporation of semen into the semen extender composition. Some claims are/are further drawn to the method of making the semen extender composition by mixing the components of the composition. Some claims are further drawn to the use of surfactant such as sodium lauryl sulfate in the semen extender composition. Some claims are further drawn to the use of antioxidants such as vitamin A or vitamin E in the semen extender composition. Some claims are further drawn to the use of to the use of specific concentrations of anti-oxidant(s) in the semen extender composition.

EP 0 685 556 and/or US 6,368,786 are relied upon as explained above for the disclosure of semen extender compositions. EP 0 685 556 is lacking disclosure about the use of specific antioxidant such as vitamin A. However, US 6,368,786 teaches incorporation of antioxidant vitamin A accompanied and additional surfactant including Tween 80 into the semen extender composition.

Thus, the cited EP 0 685 556 and US 6,368,786 are lacking disclosure about the use of particular vitamins such as vitamin E and the use of particular surfactant such as sodium lauryl sulfate.

However, the cited patent US 6,130,034 teaches incorporation of antioxidant such as vitamin E, for example: see col. 1, line 50, as a commonly used and/or regular component in the composition intended for semen transportation and storage (col. 1, line 29). The suggested concentration for anti-oxidant vitamin E is 1mM (col. 1, line 54).

Further, the reference by Hellmann et al. teaches the use of surfactant sodium lauryl sulfate in the composition intended for animal semen preservation (see abstract).

In addition, US 3,444,039 is relied upon to demonstrate that sodium citrate buffering preparation that is commonly used composition intended for semen preservation including semen extender compositions of EP 0 685 556 and/or US 6,368,786 provides for neutral pH of about 6 - 7 and osmolarity of about 250-300 mOsm which are regular pH and osmolarity parameters for animal cell culture maintenance and preservation (see col. 2, line 6 or see col. 3, line 30 and 44). And the cited US 6,140,121 teaches incorporation of various buffers into compositions intended for semen preservation including buffers such as EDTA (col. 19, line 28) or Tris or sodium citrate as well as polyoxyethylene sorbitan which is Tween 80 within the medium M199 in the composition intended for freezing sperm (col. 16, lines 57-59).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to incorporate ingredients such as various antioxidants and various surfactants into the semen extender composition as required by the presently claimed invention with a reasonable expectation of success in obtaining composition suitable for semen

maintenance and/or preservation because these compositions and ingredients have been known and commonly used in the field of semen maintenance and preservation as adequately demonstrated by the cited references in combination. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Response to Arguments

Applicants' arguments filed 8/18/2006 have been fully considered and the contents of Declaration by Dr. Richard B. Lomneth filed 4/04/2005 have been reviewed but they are not persuasive for the reasons below.

1. With regard to the claim rejection under 35 U.S.C. 102(b) as being anticipated by EP 0 685 556 (Ghazarian) applicants argue that the cited composition lacks "anionic" surfactant (response page 10). Applicants' definitions of an anionic surfactant are based on the Rosen's definitions (Exhibit filed 8/18/2006) wherein a generic anionic surfactant is defined as a substance that bears a negative charge and that would be present in interface (response page 7). Thus, the soybean lecithin of the cited EP 685 556 is an anionic surfactant since it bears a negative charge of the group PO_4^- and it would be present in interface since it has amphipathic structure comprising lyophobic and lyophilic groups in view of the Rosen's definitions (pages 3-4).

Furthermore, regardless common use of TRIS as a buffering agent, TRIS is also an emulsifying agent as taught by MERCK, for example: see page 1664 of The MERCK INDEX.

1996. 12th edition (cited on form PTO 892 mailed 10/29/2004). The emulsifying agents exert an inhibitory effect on freezing denaturation by inhibiting the formation of ice crystal, for example: see col. 3, lines 52-54 of US 6,641,853. Thus, TRIS, as being an emulsifying agent, is reasonably expected to provide for the claimed effect of reducing ice crystal formation in the composition of the cited EP 0 685 556 (Ghazarian).

The presently claimed component (b) is a generic agent having a genetic function. The claimed component (b) is not necessarily one specific ingredient as argued. The cited composition of EP 0 685 556 (Ghazarian) contains various agents that would functions as surfactants and that would also provide function such as “to reduce ice crystal formation during freezing”, for example: glycerol, fructose, glucose, etc. The claimed composition also contains various agents that would have double functions, for example: carbohydrate such as fructose, for example, is also a freezing agent; glycerol is a freezing agent and also surfactant. Therefore, the cited composition contains the presently claimed generic component (b) having generic function(s) of surfactant. Thus, the cited composition is not different from the presently claimed composition.

2. With regard to the claim rejection over US 6,368,786 (Saint-Ramon et al.) applicants presented Declaration by Dr. Richard Lomneth (filed 4/04/2005) as evidence intended to demonstrate a reduction to practice of the instant patent application prior to May 14, 1999 (priority date of US 6,368,786).

The contents of the Declaration and arguments based thereon have been fully reviewed. The arguments are based on the experiments disclosed on the laboratory notebook pages 1-6 (Exhibit A, filed with Declaration on 4/04/2005) describing incorporation of BILADYL product,

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lecithin and Equex (sodium lauryl sulfate) into the semen extender composition(s). The BILADYL concentrate product does not contain the animal derived phospholipids as evidenced by the Exhibit filed with the last response (8/18/2006). However, upon review of the laboratory notebook pages, it appears that the laboratory notebook pages are silent about source of the purified lecithin disclosed therein and that the laboratory notebook pages do not contain any information that the purified lecithin described therein is not from the animal source as encompassed by the present application and claims.

Therefore, the contents of the Declaration and arguments based thereon with regard to priority date(s) are not persuasive.

3. With regard to claim rejection under 35 USC § 103 applicants argue that there is no suggestion to combine references (response pages 11-13). However, the cited references are in the same field of endeavor (such as compositions intended for semen storage or preservation) and they seek to solve the same problems as the instant application and claims (such as provide for a semen extender composition), and one of skill in the art is free to select components available in the prior art, *In re Winslow*, 151 USPQ 48 (CCPA, 1966).

In particular, with regard to EP 0 685 556 [Ghazarian] applicants argue that it fails to disclose the use of an "anionic surfactant". This argument is not found persuasive because the prior art as a whole recognizes incorporation of surfactants including incorporation specific anionic surfactant such as sodium lauryl sulfate into the semen extender composition as adequately taught by the reference by Hellemann et al., for example.

With regard to the cited patents US 3,444,039 {Rajamannan}, US 6,130,034 {Aitken} and the reference by Hellmann et al applicants appear to argue (response pages 12-13) that the

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cited compositions contain animal derived phospholipids from egg yolk. However, these prior art references are relied upon for the teaching about other than phospholipids components as explained above. Moreover, the cited US 6,140,121 [Ellington et al] and US 6,368,786 [Saint-Ramon et al] clearly teach exclusion of egg products since the animal products including egg products might carry pathogens. For example: see US 6,140,121 at col. 27, line 16-30; see US 6,368,786 at col.1, lines 22-25. The cited EP 0 685 556 {Ghazarian et al.} and by US 6,368,786 {Saint-Ramon et al.} disclose compositions with non-animal derived phospholipids such as soy lecithin. And the cited US 6,140,121 {Ellington} suggests incorporation of soy lecithin as alternative to egg yolk for the non-egg yolk containing semen extenders (page 27, lines 20-30).

Motivation to combine the prior art teaching can come not only from direct teaching of the prior art, but also the nature of the problem to be solved and/or the knowledge of persons of ordinary skill in the art, *Ruiz v. A.B. Chance Co.* 357 F.3d 1270, 69 USPQ2d 1686 (2004). Further, the examiner recognizes that references cannot be arbitrarily combined that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references, *In re Nomiya*, 184 USPQ 607 (CCPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. One test for combining references is what the combination of disclosures taken as a whole would suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969). In this case, the use of components known in the art, and used for their known art specific properties even in different combinations, is considered to be obvious in the absence of evidence to the contrary.

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Furthermore, with respect to the contents of the Declaration by Dr. Richard Lomneth (filed 4/04/2005) it is noted that the particular compositions reported in Declaration (4/04/2005) appear to be different from the particular compositions disclosed in the instant specification (pages 17-19) to consider the possibilities of unexpected results, if any. Thus, the advantage that is not disclosed in the specification cannot be urged as basis for allowing claims. *In re Lundeborg*, 117 USPQ 190 (CCPA 1958).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

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October 31, 2007



VERA AFREMOVA
PRIMARY EXAMINER